

# Exhibit O


**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Office of the Secretary

The General Counsel  
Washington, D.C. 20201

**ADVISORY OPINION 21-01 ON THE  
PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT  
SCOPE OF PREEMPTION PROVISION  
JANUARY 8, 2021**

Following the issuance by the Secretary on December 3, 2020, of the Fourth Amendment to his Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, we have received questions as to whether the PREP Act applies where a covered person declined to use a covered countermeasure when it arguably ought to have been used.<sup>1</sup> See 85 Fed. Reg. 79,190 (Dec. 9, 2020). These inquiries were stimulated, as we understand, by a spate of recent lawsuits, most involving nursing homes and other healthcare facilities, where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with personal protective equipment (“PPE”), failed to teach the staff how to properly use that equipment, or failed to ensure that its staff used the PPE that it had been given. This Advisory Opinion addresses these questions in the context of our administration of the PREP Act and the Secretary’s PREP Act Declaration, as amended.

### **I. Analysis**

There has been a growing number of suits related to the use or non-use of covered countermeasures against COVID-19, including PPE. These cases tend to be filed in state courts alleging a variety of state law-based torts. In this “jurisprudential Kabuki dance” (*Maine Public Utilities Com'n v. F.E.R.C.*, 625 F.3d 754, 758 (D.C. Cir. 2010)), defendants file removal petitions and plaintiffs respond with remand motions. To resolve the remand motions, courts first assess whether the doctrine of complete preemption applies. Ordinary preemption is a defense and does not support Article III subject matter jurisdiction (usually under 28 U.S.C. § 1331), a prerequisite for removal. See *Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804 (1986). In contrast, complete preemption is “really a jurisdictional rather than a preemption doctrine, [as it] confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim.” *Marin General Hosp. v. Modesto & Empire Traction Co.*, 581 F.3d 941, 945 (9th Cir. 2009) (quoting *Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Trust Fund*, 538 F.3d 594, 596 (7th Cir. 2008) (internal quotations omitted)). Relatively few statutes completely preempt.

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<sup>1</sup> The PREP Act is the Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, div. C, § 2, 119 Stat. 2818 (Dec. 30, 2005), codified at 42 U.S.C. §§ 247d-6d, 247d-6e. It has been amended through the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, title IV, § 402(g)(2), (3), 127 Stat. 196 (Mar. 13, 2013) and further amended by § 6005 of the Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 177 (March 18, 2020) and § 3103 of the Coronavirus Aid Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (March 27, 2020).

#### A. The PREP Act is a “Complete Preemption” Statute

The Supreme Court first articulated the doctrine of complete preemption as a basis for federal question removal jurisdiction under 28 U.S.C. § 1441(a) in *Avco Corp. v. Aero Lodge No. 735, Intern. Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557, 559 (1968) (holding that the Labor Management Relations Act, 1947 completely preempted state court jurisdiction). Thereafter, the doctrine was extended to the Employee Retirement Income Security Act of 1974 in 1987, the National Bank Act in 2003, and the Air Transportation Safety and System Stability Act in 2005. *See Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58 (1987) (ERISA completely preempts state law); *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) (the same); *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7–11 (2003) (National Bank Act completely preempts); *In re WTC Disaster Site*, 414 F.3d 352, 375 (2d Cir. 2005) (Air Transportation Safety and System Stability Act completely preempted state claims and ousted state courts of jurisdiction by creating an exclusive federal cause of action). The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.

Once complete preemption attaches, the district court is usually obligated to dismiss the case as pleaded, either because no federal cause of action is alleged or the exclusive initial venue is a federal administrative agency.

All that is well and good, but it does not address the issue that appears to have perplexed district courts, namely when is the PREP Act triggered. District courts appear to have labored hard attempting to ordain whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime. At one extreme, plaintiff may have pleaded that the facility failed *in toto* to provide any of its staff or patients with any PPE, a covered countermeasure if NIOSH approved or FDA cleared or waived. Other plaintiffs allege that the quantity of PPE was inadequate, that staff were not timely provided PPE or that staff were not adequately trained to use PPE. The latter three complaints reflect many of the complaints that we have reviewed.

The PREP Act’s immunity provision, which triggers exclusive federal jurisdiction, states as follows:

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

Public Health Service Act § 319F-3(a)(1), 42 U.S.C. § 247d-6d(a)(1) (emphasis supplied).

The PREP Act goes on to provide that its immunity

applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal

relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

*Id.* at § 319F-3(a)(2)(B), 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis supplied).

Some district courts have interpreted the scope of the immunity in subparagraph (B) as requiring “use.” Under this view, if a covered countermeasure were not used, then there is no PREP Act immunity. According to one court, “[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of a covered countermeasure.” *Lutz v. Big Blue Healthcare, Inc.*, \_\_\_ F. Supp. 3d \_\_\_, 2020 WL 4815100, at \*8 (D. Kan. 2020) (emphasis in original) (granted remand motion).

However, this “black and white” view clashes with the plain language of the PREP Act, which extends immunity to anything “relating to” the administration of a covered countermeasure. For example, consider a situation where there is only one dose of a COVID-19 vaccine,<sup>2</sup> and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID-19. In that circumstance, the failure to administer the COVID-19 vaccine to the person in a less-vulnerable population “relat[es] to . . . the administration to” the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act and this Declaration’s liability protections. There can potentially be other situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure. In contrast, the failure to purchase any PPE, if not the outcome of some form of decision-making process may not be sufficient to trigger the PREP Act.

Where a facility has been allocated a scarce therapeutic purchased by the federal government and that facility fails to administer that therapeutic to an individual who meets the requirements of the FDA’s authorization, approval, or license, and whose physician prescribes that therapeutic, then the facility’s refusal to administer that therapeutic could still trigger the PREP Act assuming the non-use of the therapeutic was the result of conscious decision-making. However, the facility may still be liable under the PREP Act, if the plaintiff alleges that the decision to deny him or her the therapeutic was wanton and willful and resulted in death or serious injury. *See* 42 U.S.C. § 247d-6d(d)-(e). Such a case would be transferred to the District Court for the District of Columbia for resolution by a three-judge panel. The facility may also be subject to a federal enforcement action.

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<sup>2</sup> For simplicity, this example assumes a patient only requires one dose of the vaccine.

The language of the PREP Act itself supports a distinction between allocation which results in non-use by some individuals, on the one hand, and nonfeasance, on the other hand, that also results in non-use.

Included within the set of “covered persons,” *i.e.*, those entitled to immunity, are “program planners.” 42 U.S.C. § 247d-6d(i)(2)(B)(iii). A “program planner” is

a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

*Id.* at § 247d-6d(i)(6).

A program planner is someone who is involved in providing or allocating covered countermeasures. Program planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them. Therefore, decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act

There are going to be circumstances where plaintiff pleads that defendant’s culpability is the result of its failure to make any decisions whatsoever, thereby abandoning its duty to act as a program planner or other covered person. Although this is a small hole through which to wiggle to avoid complete preemption, we are confident, were it not for two legal constraints, that it would grow as plaintiffs become more adept at fashioning their pleadings. However, “complete preemption . . . functions as an exception to the well-pleaded complaint rule.” *Giles v. NYLCare Health Plans, Inc.*, 172 F.3d 332, 336 (5th Cir. 1999). Thus, federal courts are free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint. See *United Surgical Assistants, LLC v. Aetna Life Ins. Co.*, 2014 WL 4059889, at \*1 (M.D. Fla. Aug. 14, 2014) (allowing jurisdictional discovery on whether plaintiff’s claim was completely preempted by ERISA).

## **B. Fourth Amendment to the Secretary’s Declaration Supports the *Grable* Doctrine**

In addition to complete preemption as the basis for article III jurisdiction and removal, the Court recognized a separate doctrine in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308 (2005). Under *Grable*, even in the absence of a claim arising under federal law, “a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 312 (2005) (emphasis supplied). Thus, a substantial federal question is implicated, for example, where “the

interpretation of a federal statute [ ] actually is in dispute in the litigation and is so important that it sensibly belongs in federal court.” 545 U.S. at 315. Here, ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court. The Secretary, in his Fourth Amendment to his PREP Declaration, similarly concluded, when he stated that

[t]here are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.

85 Fed. Reg. at 79,197 (col. c).

*See also* 42 U.S.C. § 247d-6d(b)(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.”). As such, the secretarial determination provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure. Once invoked, the court retains the case to decide whether the immunity and preemption provisions apply; if they do not apply, then the court would try the case as it would a diversity case. If the court finds, though, that the PREP Act applies, it would dismiss the case or if death or serious physical injury proximately caused by willful misconduct is alleged, transfer it to the District Court for the District of Columbia. *See* 42 U.S.C. § 247d-6d(d)-(e).

## II. Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.<sup>3</sup> It is not a final agency action or a final order. It does not have the force or effect of law.

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<sup>3</sup> See *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).